DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Elitek
Docket No.: 03E-0249

JUN 23 2004

The Honorable Jon Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,382,518, filed by Sanofi-Synthelabo, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Elitek, the human biological product claimed by the patent.

The total length of the regulatory review period for Elitek is 2,360 days. Of this time, 1,420 days occurred during the testing phase and 940 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: January 27, 1996.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 27, 1996.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: December 16, 1999.

   FDA has verified the applicant's claim that the product license application (BLA) for Elitek (BLA 103946/0) was initially submitted on December 16, 1999.

3. The date the application was approved: July 12, 2002.

   FDA has verified the applicant's claim that BLA 103946/0 was approved on July 12, 2002.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Michael D. Alexander
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